Initial Approval: July 2005
Revised Date: October 8, 2014
July 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Xolair® (omalizumab)

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Omalizumab (Xolair)

CRITERIA FOR ALLERGIC ASTHMA Must meet all of the following:

- Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist
- Patient must have a diagnosis of moderate to severe persistent asthma diagnosis for at least 1 year (diagnosis must be based upon NHLBI criteria – see attached table)
- Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen
- Patient must be 12 years of age or older
- Patient must be taking and be compliant with a high-dose inhaled corticosteroid and a long-acting $beta_2$-agonist
- Patient must have symptoms that are not well controlled while compliant with asthma controller medication (based upon NHLBI criteria – see attached table)
- Dosing must be based upon attached table

RENEWAL CRITERIA FOR ASTHMA Must meet all of the following:

- Documentation of monthly injections. If patient has missed 2 or more injections the renewal request will be denied based upon non-compliance
- Patient must have documented improvement in lung function test: FEV1 of at least 12% or PEF of at least 20%
- Patient must have a documented decrease in the number of asthma exacerbations and symptomatic improvement per physician assessment

CRITERIA FOR CHRONIC IDIOPATHIC URTICARIA Must meet all of the following:

- Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist
- Patient must have a diagnosis of chronic idiopathic urticaria
- Patient must be 12 years of age or older
- Patient must be symptomatic despite H1 antihistamine treatment
- Dosing must not exceed 300mg every 4 weeks

LENGTH OF APPROVAL 6 months

APPROVED PA Criteria

Classification of Asthma Severity

Adapted from NHLBI Guidelines for the Diagnosis and Management of Asthma*

Components of Severity		Classification of Asthma Severity ≥12 years of age			
		Intermittent	Persistent		
			Mild	Moderate	Severe
Impairment **Normal FEV_1/FVC:** **8-19 yr 85%** **20-39 yr 80%** **40-59 yr 75%** **60-80 yr 70%**	Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout Day
	Nighttime awakenings	≤2x/month	3-4x/month	>1x/week but not nightly	Often 7x/week
	Short-acting $beta_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily, and not more than 1x on any day	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung Function	• Normal FEV_1 between exacerbations • FEV_1 >80% predicted • FEV_1/FVC normal	• FEV_1 >80% predicted • FEV_1/FVC normal	• FEV_1 >60% but <80% predicted • FEV_1/FVC reduced 5%	• FEV_1 <60% predicted • FEV_1/FVC reduced >5%

Classification of Asthma Control

Adapted from NHLBI Guidelines for the Diagnosis and Management of Asthma*

Components of Control		Classification of Asthma Control ≥12 years of age		
		Well Controlled	Not Well Controlled	Very Poorly Controlled
Impairment	Symptoms	≤2 days/week	>2 days/week but not daily	Throughout the day
	Nighttime awakenings	≤2x/month	1-3x/week	≥4x/week
	Interference with normal activity	None	Some limitation	Extremely limited
	Short-acting $beta_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	FEV_1 or peak flow	>80% predicted/personal best	60-80% predicted/personal best	<60% predicted/personal best
	Validated questionnaires • ATAQ • ACQ • ACT	• 0 • ≤0.75* • ≥20	• 1-2 • ≥1.5 • 16-19	• 3-4 • N/A • ≤15

*ACQ values of 0.76-1.4 are indeterminate regarding well-controlled asthma

APPROVED PA Criteria

Dosing Table 1

Administration every 4 weeks

Xolair Dose (mg) administered by subcutaneous injection

Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	> 60-70 kg	> 70-90 kg	> 90-150 kg
≥30-100	150mg	150mg	150mg	300mg
>100-200	300mg	300mg	300mg	
>200-300	300mg	**See Dosing Table 2**		
>300-400				
>400-500				
>500-600				

Dosing Table 2

Administration every 2 weeks

Xolair Dose (mg) administered by subcutaneous injection

Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	>60-70 kg	>70-90 kg	>90-150 kg
≥30-100	**See Dosing Table 1**			
>100-200				225mg
>200-300		225mg	225mg	300mg
>300-400	225mg	225mg	300mg	
>400-500	300mg	300mg	375mg	
>500-600	300mg	375mg	**Do Not Dose**	
>600-700	375mg			

***References:**

Xolair®[package insert]. South San Francisco, CA: Genetech, Inc; March 2014.

National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma 2007. Bethesda, MD: National Institutes of Health; August 2007. NIH Publication 07-4051.